APR 2 8 2004

K040804
Page 1 of 2

Section 807.87 (h) A 510(k) Summary as described in Section 807.92 or a 510(k) statement as described in 807.93

Premarket Notification [510(k)] Summary as required by 21 CFR 807.92

Date summary was prepared:

March 24, 2004

Submitter's Name:

Southeastern Radiation Products, Inc.
2651 North Design Court
Sanford, Florida 32773

Contact Person:

Linda Moon
Quality Manager
Phone: 407-330-3300
Fax: 407-322-7546
Email:quality@seradiation.com

Device Name:

.decimal tissue compensator / intensity modulator manufacturing service

Classification Name:

Class II

Predicate Device(s):

CMS	K0000137	
NOMOS	K940412	(as referred to in CMS' 510(k) submission)
Varian	K943224	(as referred to in CMS' 510(k) submission)
PAR Scientific	K021987	
Huestis	K880047	

K042804
Page 2 of 2

Intended Use:

.decimal tissue compensator/intensity modulator manufacturing service manufactures the solid filters for missing tissue and intensity modulation for external beam radiation therapy.

Technological Characteristics:

The technological characteristics of .decimal are discussed in Southeastern Radiation Product's attached documents:

DMR-03 Device Master Record – .decimal Tissue Compensators
PD-03 Processing a .decimal tissue Compensator Work Order
MSDS Sheet for 6061-T6 Aluminum and 360 Brass

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 8 2004

Mr. Richard Sweat
President
Southeastern Radiation Products, Inc.
2651 N. Design Court
SANFORD FL 32773

Re: K040804
Trade/Device Name: .decimal Tissue Compensator/Intensity Modulator
Regulation Number: 21 CFR 892.5710
Regulation Name: Radiation therapy beam-shaping block
Regulatory Class: II
Product Code: 90 IXI
Dated: March 24, 2004
Received: March 29, 2004

Dear Mr. Sweat:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known) K040804

Device Name: .decimal Tissue Compensator/Intensity Modulator

Indication for Use:

.decimal tissue compensator/intensity modulator manufacturing service manufactures the solid filters for missing tissue and intensity modulation for external beam radiation therapy.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

David R. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040804